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A61B 17/70 (2006.01) A61F 2/44 (2006.01)(71) Applicants and  
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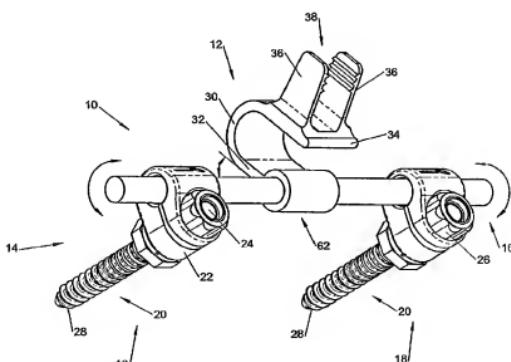
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG

{Continued on next page}

(54) Title: INTERSPINOUS VERTEBRAL AND LUMBOSACRAL STABILIZATION DEVICES AND METHODS OF USE



(57) Abstract: Implantable devices are provided for stabilizing adjacent vertebrae and the lumbosacral region of a patient. The devices can comprise an interspinous flexible spacer body (12) having a substantially U-shape comprising a superior section (34), inferior section (32), and a midsection (30) extending therebetween. The superior and/or inferior sections can include a pair of lateral walls (36) configured to engage a spinous process of a vertebra. Fixation caps can be provided for securing a spinous process of a vertebra to the flexible spacer body. To secure the flexible spacer body between the lumbar vertebra and an adjacent vertebra, an anchor assembly (14) is provided. Also provided are methods of using the implantable devices to stabilize a patient's spine.

A3

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SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/013150A. CLASSIFICATION OF SUBJECT MATTER  
INV. A61B17/70 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	-/-	

 Further documents are listed in the continuation of Box C. See patent family annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the International filing date
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- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the International search

16 October 2006

Date of mailing of the International search report

26/10/2006

Name and mailing address of the ISA/

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## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2006/013150

## C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 645 599 A (SAMANI ET AL) 8 July 1997 (1997-07-08) cited in the application	1-3, 8, 9, 11-15, 21-23, 36-38, 53-55, 58-60, 121-124, 132-136, 140, 145, 146, 148-152, 158-160, 174-176
Y	the whole document	7, 10, 16-20, 23, 39-45, 49, 50, 52, 61-63, 67, 68, 72, 75-91, 106-113, 117, 118, 120, 127-130, 137-139, 144, 147, 153-157 160, 182, 185, 223, 224, 227-231, 238, 240, 246-249, 254, 256-258, 261-268, 291, 292, 283-285
Y		
A	-----	-/-

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/013150

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 330 987 A (BIOMET MERCK FRANCE; ELBERG, JEAN-FRANCOIS; INDUSTRIAS QUIRURGICAS DE) 30 July 2003 (2003-07-30) column 3, paragraph 23 - column 6, paragraph 41 figures 3,7,8	7,75,144
A		1-3,8,9, 21,22, 36,39, 40,43, 49, 53-55, 58-60, 63,72, 111,117, 121-123, 132-136, 140,145, 146,149, 158,159, 174
Y	----- WO 99/40866 A (DIMSO ; ELBERG, JEAN-FRANCOIS; CLOIX, ERICK) 19 August 1999 (1999-08-19)	16,17, 84,85, 153,154, 185,186, 236,237, 254,255, 281,282
A	page 5, line 28 - page 10, line 5 figures 1-5	1-3,7-9, 12,21, 22,36, 53-55, 58-60, 63, 121-123, 132-136, 140, 144-146, 149,158, 159,174, 182,232, 248
	----- -/-	

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/013150

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/216736 A1 (ROBINSON JAMES C ET AL) 20 November 2003 (2003-11-20) page 1, paragraphs 4,5,7 page 2, paragraph 20 figure 3	62,139
A		1,16,17, 84,85, 121,153, 154,185, 186,236, 237,254, 255,281, 282
A	EP 0 649 636 A (JOHNSON & JOHNSON PROFESSIONAL INC) 26 April 1995 (1995-04-26) column 1, lines 3-13 figures 1-3	1,13-15, 121, 150-152
Y	FR 2 703 239 A (BRIOT BIO RHONE IMPLANT MEDICAL) 7 October 1994 (1994-10-07) page 1, lines 1-34 page 2, line 18 - page 3, line 4 figures 2,3	107,108, 279,280
A		1,36-38, 63,121, 174-176, 269,277, 278
Y	US 5 868 745 A (ALLEYNE NEVILLE [US]) 9 February 1999 (1999-02-09) column 3, lines 18-33 claim 1 figures 3A-4B	10,78, 147
A		1,63,121
A	US 4 773 402 A (ASHER MARC A [US] ET AL) 27 September 1988 (1988-09-27) column 3, lines 27-40 figure 1	1,10,78, 121,147
Y	EP 0 806 212 A1 (MATRIX MEDICAL B V [NL]) ISOTIS N V [NL]) 12 November 1997 (1997-11-12)	18-20, 86-88, 155-157, 227-229, 243-245, 261-263, 288-290
A	page 2, line 3 - page 3, line 41 claims 1,2,6,8	1,63,121
	----- -/-	

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/013150

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 761 720 B1 (SENEGAS JACQUES [FR]) 13 July 2004 (2004-07-13) column 1, lines 3-56 column 3, line 1 - column 4, line 17 figure 1	232,234, 236,239
Y		23,91, 160,182, 185,186, 223,224, 227-231, 236-238, 240, 243-249, 254-258, 261-268 1,63, 121,279
A		
X	FR 2 717 675 A1 (TAYLOR JEAN [FR]) 29 September 1995 (1995-09-29) page 5, line 24 - page 7, line 23 figure 1	232,236, 239
A		1,23, 121,160, 182
X	US 5 496 318 A (HOWLAND ROBERT S [US] ET AL) 5 March 1996 (1996-03-05) column 3, line 28 - column 4, line 42 figures 1-3	269,273, 277,278
Y		279-282, 288-292
A		1,30,33, 98,102, 121,167, 171,177, 180
Y	EP 1 138 268 A (COUSIN BIOTECH S A S [FR]; TAYLOR JEAN [FR]) 4 October 2001 (2001-10-04)	39-45, 49,50, 52,61, 63,67, 68,72, 75-91, 106-113, 117,118, 120, 127-130, 137,138
A	column 1, paragraph 1 column 3, paragraph 22 - column 4, paragraph 28 figure 7	1,121
	-----	-/-

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/013150

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 810 815 A (MORALES JOSE A [MX]) 22 September 1998 (1998-09-22)  column 2, line 6 - column 3, line 23 figure 1  -----	1,39,47, 49,63, 121
A	WO 2005/020860 A2 (SPINE NEXT [FR]; PASQUET DENIS [FR]; LE COUEDIC REGIS [FR]; SENEGAS JA) 10 March 2005 (2005-03-10)  page 6, line 3 - page 10, line 36 figure 6  -----	1,61,63, 121,129, 131,137, 138
A	US 6 364 883 B1 (SANTILLI ALBERT N [US]) 2 April 2002 (2002-04-02) column 2, line 66 - column 4, line 2 figures 3,4  -----	121,180

**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/US2006/013150**Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: **293-319** because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery**
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/USA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims:

1-9, 11-17, 21, 22, 36-38, 53-55, 58-60, 62,  
121-124, 132-136, 139-146, 148-15  
4, 158, 159, 174-176

An implantable device for stabilizing a lumbar region of a patient having variable flexibility.  
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2. claims: 10, 147

Malleable properties of an implantable device for stabilizing a lumbar region of a patient.  
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3. claims: 18-20, 155-157

An implantable device for stabilizing a lumbar region of a patient containing biologically active materials.  
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4. claims: 23-29, 160-166, 182-268

Closure means for an implantable device for stabilizing a lumbar region of a patient.  
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5. claims: 30-35, 56, 57, 125, 126, 167-173, 269-292

An implantable device for stabilizing a lumbar region of a patient having selectively movable lateral walls.  
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6. claims: 39-52, 63-120, 127-131

An implantable device for stabilizing a lumbar region of a patient including an anchor assembly comprising a support rod.  
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7. claims: 61, 137, 138

An implantable device for stabilizing a lumbar region of a patient having a system for securing the device within the sacral canal.  
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8. claims: 177-181

Multi-component construction of an implantable device of the type claimed.  
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**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/013150

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5645599	A 08-07-1997	FR 2722980 A1		02-02-1996
		JP 3631293 B2		23-03-2005
		JP 8052166 A		27-02-1996
EP 1330987	A 30-07-2003	AT 290341 T		15-03-2005
		DE 60203159 D1		14-04-2005
		DE 60203159 T2		11-05-2006
		ES 2236470 T3		16-07-2005
		FR 2835173 A1		01-08-2003
		PT 1330987 T		31-05-2005
WO 9940866	A 19-08-1999	AT 303104 T		15-09-2005
		AU 2428399 A		30-08-1999
		CA 2320821 A1		19-08-1999
		DE 69926995 D1		05-10-2005
		DE 1054638 T1		03-05-2001
		EP 1054638 A1		29-11-2000
		ES 2151876 T1		16-01-2001
		FR 2774581 A1		13-08-1999
		JP 2002502662 T		29-01-2002
		US 6440169 B1		27-08-2002
US 2003216736	A1 20-11-2003	AU 2003225270 A1		12-12-2003
		CA 2485174 A1		04-12-2003
		CN 1652727 A		10-08-2005
		EP 1418854 A1		19-05-2004
		JP 2005525907 T		02-09-2005
		WO 03099147 A1		04-12-2003
EP 0649636	A 26-04-1995	BR 9403774 A		23-05-1995
		CA 2132370 A1		21-03-1995
		DE 69410055 D1		10-06-1998
		JP 3615797 B2		02-02-2005
		JP 7163583 A		27-06-1995
		US 5417690 A		23-05-1995
FR 2703239	A 07-10-1994	NONE		
US 5868745	A 09-02-1999	NONE		
US 4773402	A 27-09-1988	NONE		
EP 0806212	A1 12-11-1997	NONE		
US 6761720	B1 13-07-2004	AT 285714 T		15-01-2005
		AU 775274 B2		29-07-2004
		AU 7800500 A		30-04-2001
		BR 0014764 A		11-06-2002
		CA 2387589 A1		26-04-2001
		CZ 20021288 A3		14-08-2002
		DE 60017164 D1		03-02-2005
		DE 60017164 T2		29-09-2005
		EP 1220644 A1		10-07-2002
		ES 2234676 T3		01-07-2005
		WO 0128442 A1		26-04-2001
		FR 2799640 A1		20-04-2001
		HU 0203511 A2		28-02-2003
		JP 2003516173 T		13-05-2003

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No  
PCT/US2006/013150

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 6761720	B1	MX	PA02003813 A	13-12-2002
		NZ	518681 A	26-03-2004
		PL	354534 A1	26-01-2004
		RU	2243747 C2	10-01-2005
		TR	200200984 T2	21-01-2003
		TW	542713 B	21-07-2003
		UA	71639 C2	15-07-2002
		ZA	200202896 A	14-04-2003
FR 2717675	A1	29-09-1995	NONE	
US 5496318	A	05-03-1996	NONE	
EP 1138268	A	04-10-2001	FR	2806616 A1
US 5810815	A	22-09-1998	NONE	28-09-2001
WO 2005020860	A2	10-03-2005	AU	2004268404 A1
			EP	1656075 A2
			FR	2858929 A1
US 6364883	B1	02-04-2002	NONE	